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|--------------------------|-----------------------------------|--------------------------------|--|
| Interview Summary | Application No. 09/882,889 | Applicant(s) HADDOCK ET AL. | |
| | Examiner Charles A. Marmor, II | Art Unit 3736 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Charles A. Marmor, II. (3) _____

(2) John G. Posa. (4) _____

Date of Interview: 29 October 2002.

Type: a) ☐ Telephonic b) ☐ Video Conference
c) ☒ Personal [copy given to: 1) ☐ applicant 2) ☒ applicant's representative]

Exhibit shown or demonstration conducted: d) ☐ Yes e) ☒ No.
If Yes, brief description: _____.

Claim(s) discussed: 1 and 6.

Identification of prior art discussed: Naghavi et al. and Brown.

Agreement with respect to the claims f) ☒ was reached. g) ☐ was not reached. h) ☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant submitted a proposed amendment for purposes of discussion. The proposed amendments apparently overcome the rejections under 35 USC 102 and 103 made in the Office Action dated 12 August 2002. The search will be updated upon submission of a formal amendment.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

i) ☐ It is not necessary for applicant to provide a separate record of the substance of the interview(if box is checked).

Unless the paragraph above has been checked, THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.


Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

GIFFORD, KRASS, GROH, SPRINKLE,
ANDERSON & CITKOWSKI, P.C.
101 North Main St., Suite 800
Ann Arbor, Michigan 48104-1476

(734) 913-9300
FACSIMILE (734) 913-6007
jposa@patlaw.com
dwathen@patlaw.com

FACSIMILE TRANSMISSION

DATE: October 28, 2002

TO: EXAMINER CHARLES MARMOR II

FACSIMILE NO.: 703/746-3335

FROM: John G. Posa

PAGES TRANSMITTED (INCLUDING COVER SHEET): 14

ORIGINAL DOCUMENTS WILL ___ WILL NOT X FOLLOW BY MAIL

RE: SN 09/882,889

MESSAGE:

Examiner Marmor:

Attached is a Proposed Amendment for your review prior to our scheduled interview on Tuesday, October 29 at 2:00 pm.

Information contained in this facsimile may be PRIVILEGED and CONFIDENTIAL. It is intended only for the use of the person or entity named above. If you are not the intended recipient, you are hereby notified that any dissemination, distribution, or copying of this communication is neither intended nor permissible. If this facsimile has been received in error, please notify us immediately (call collect) and return the facsimile to us.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Haddock et al.

Serial No.: 09/882,889

Group No.: 3736

Filed: June 15, 2001

Examiner: C. Marmor II

For: TEMPERATURE SENSING CATHETER

PROPOSED AMENDMENT
FOR DISCUSSION PURPOSES ONLY

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

In response to the Office Action mailed August 12, 2002, please amend the above-referenced application as follows:

IN THE SPECIFICATION:

Replace the paragraph on page 8, lines 8-9 with the following:

FIGURE 1D shows how the insulating capability of an expanding pad increases with increasing outside diameter (O.D.) for a given sensor size;

Replace the paragraph on page 16, lines 11-18 with the following:

As with the other embodiments disclosed herein, preferably the materials forming the fingers 302 in this case are insulated against blood flow temperature variations so that the sensors 304 accurately record wall temperatures without being adversely affected by blood flow. This embodiment is also not restricted to the use of two fingers, but more may be used such as the three fingers shown in Figure 3C. In addition, as with the other embodiments described herein, the embodiment described with

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reference to Figures 3A through 3C may also be calibrated so as to provide a user with an estimate of inner vessel diameter as well as localized temperature.

Replace the paragraph on page 16, line 19 to page 17, line 4 with the following:

Figures 4A through 4D illustrate preferred hand-type embodiments of the invention. In Figure 4A, a sensing head 402 includes one or more sensing cantilevered arms 404, each with a thermal sensor, surrounding a central member 410. The arms and central member are configured such that when the member is pulled from the proximal end, the arms fan outwardly from the contracted state of Figure 4A into a the expanded position, as shown in Figure 4B. Again, the arms are cantilevered to provide a relatively constant and uniform force against the vessel wall in the expanded state while avoiding excess pressure.

Replace the paragraph on page 19, lines 9-18 with the following:

The temperature sensors are preferably embedded slightly below the outer surfaces of the sensing arms or elements, along the surface closest to the inner wall of the vessel. The material covering the thermal sensor on the outer surface of the expanding element is chosen and configured so as to permit minimal thermal resistance between the thermal sensor and the outer surface of the sensing arm. This may be achieved by having a minimal thickness of material, or by choosing a material of low thermal resistance. In contrast, the bulk material of the expanding element is preferably chosen to have high thermal resistance and to be of a significantly greater thickness than the thickness of the material covering the thermal sensors on the outer surface of the sensing arms.

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IN THE CLAIMS:

Please replace current claim 1 with the following:

1. (Amended) A system for sensing the temperature of a vessel wall, including an arterial wall, the system comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including one or more presentation elements, each element having a temperature sensor supported thereon;

each presentation element having a proximal end coupled to the distal end of the catheter and a distal end coupled to the distally protruding end of the filament such that pulling on the manually operated expansion control causes each element to move from a retracted position to an expanded position enabling the sensor to be placed in contact or immediately proximate to the vessel wall, and pushing on the manually operated expansion control causes each presentation element to return to the retracted position from the expanded position; and

a data unit operative to receive electrical signals from the temperature sensors and display information indicative of vessel wall temperature.

Please replace current claim 3 with the following:

3. (Amended) The system of claim 1, wherein the presentation elements are thermally insulative so that the sensors are isolated from temperature fluctuations caused by blood flow or other ambient conditions.

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Cancel 4.

Please replace current claim 5 with the following:

5. (Amended) The system of claim 1, wherein the presentation elements are configured such that blood may continue to flow around the elements when the elements are in the expanded position.

Please replace current claim 6 with the following:

6. (Amended) A system for sensing the temperature of an arterial wall or other vessel, comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including a plurality of presentation elements in the form of cantilevered fingers which expand outwardly by pulling on the manually operated expansion control, each element having a temperature sensor supported thereon which is placed in contact or immediately proximate to the vessel wall during the expansion; and

a data unit operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors.

Please replace current claim 7 with the following:

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7. (Amended) The system of claim 6, wherein the cantilevered fingers are configured to provide a relatively constant and uniform force against the vessel wall.

Please replace current claim 8 with the following:

8. (Amended) The system of claim 6, wherein the fingers surround a central plunger coupled to the manually operated expansion control, such that pulling on the plunger causes the fingers to expand outwardly and pushing on the plunger causes the finger to turn to a contracted position.

Please replace current claim 9 with the following:

9. (Amended) The system of claim 8, wherein the plunger is conically shaped.

Please replace current claim 11 with the following:

11. (Amended) The system of claim 1, wherein the temperature sensing tip features a plurality of longitudinal slices forming a basket-like structure which flares out when the manually operated expansion control is pulled, and which collapses when the control is pushed.

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REMARKS

By this amendment, claims 1, 3, 5-9 and 11 have been amended, and claim 4 has been canceled. The amendment of claim 6 places that claim in independent form. Amendments to the specification have been made, as requested by the Examiner.

Claims 1-6, 8 and 11-15 were rejected under 35 U.S.C. §102(a) over Naghavi et al. The amendments to the claims were made to overcome the rejections under 35 U.S.C. §112, second paragraph and to better describe the way in which the instant apparatus is constructed in the way in which it operates. More particularly, whereas the Naghavi apparatus may be considered a "passive" design in the sense that, by pushing on a proximal manually operated control, the basket structure emerges from the catheter and automatically expands due to the use of shape-memory alloy, the instant invention is "active" in the sense that, by *pulling* on the manually operated control, the basket expands, and by pushing on the control, it retracts. As such, once the presentation element(s) have been pushed out of the distal tip of the catheter, they remain exposed and expand and contract by pulling and pushing on a sliding filament which extends from the proximal end.

In one embodiment of the instant invention, namely, the embodiment of claim 1, the distal end of the filament is coupled to the distal end of each presentation element, causing each element to bow outwardly and collapse inwardly as the filament is pulled and pushed, respectively. In a different embodiment, that of claim 6, now in independent form, the distal ends of the presentation elements are unattached, but nevertheless, in this embodiment as well, by pulling on the filament, being attached to a plunger or flared tip, causes the fingers to expand and contract. These structures and functions as now claimed fully distinguish over the Naghavi, such that anticipation is precluded.

Claims 1, 4-6, 8 and 9 were rejected under 35 U.S.C. §102(b) over Brown. However,

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anticipation is precluded in this case as well, because Brown is limited to optical conduits that engage with the vessel wall, carrying infrared energy to sensors that are located *outside the body*. As such, Brown does not teach or suggest the use of thermoelectric sensors such as thermistors, which use an electrical connection between the sensors, located within the body, and a data acquisition/analysis instrument located outside the body. Given that Brown clearly does not teach each and every element of Applicants' claimed invention, rejection under §102 is inappropriate.

Claim 7 stands rejected over Waldman et al. in view of Brown. It is believed that claim 7 is allowable for the reasons set forth above, but in addition, it is well settled that in rejecting claims under 35 U.S.C. §103, the Examiner must provide a reason why one having ordinary skill in the pertinent art would have been led to modify the prior art, or to combine references, to arrive at Applicants' claimed invention. There must be something *in the prior art* that suggested the combination, other than the hindsight gained from knowledge that the inventor choose to combine these particular things in this particular way. Uniroyal Inc. v. Rudkin-Wiley Corp., 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). The Examiner is also required to make specific findings on a suggestion to combine prior art references. In Re Dembiczak, 175 F.3d 994, 1000-01, 50 USPQ2d 1614, 1617-19 (Fed. Cir. 1999). In this case, Waldman is directed to an endocardial electrical mapping catheter, much larger in size than anything usable in a vessel such as an artery, with goals and solutions to problems that are irrelevant to the teachings of Brown. Likewise, the teachings of Brown are inapplicable to the Waldman et al. invention, thereby precluding *prima facie* obviousness.

Based on the foregoing, Applicants believe all claims are in condition for allowance. The provisional allowability of claim 10 has been noted. Questions regarding this application can be directed to the undersigned attorney at the telephone/facsimile numbers provided.

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Attached is a version showing the changes made to Specification and the amended claims.

Respectfully submitted,

By: _____

John G. Posa
Reg. No. 37,424
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, PC
280 N. Old Woodward Ave., Ste 400
Birmingham, MI 48009
(734) 913-9300 FAX (734) 913-6007

Date: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADEIN THE SPECIFICATION:*Page 8, lines 8-9:*

FIGURE 1D shows how the insulating capability of an expanding pad increases with increasing outside diameter (O.D.) for a given sensor size;

Page 16, lines 11-18:

As with the other embodiments disclosed herein, preferably the materials [302] forming the [arms] fingers 302 in this case are insulated against blood flow temperature variations so that the sensors 304 accurately record wall temperatures without being adversely affected by blood flow. This embodiment is also not restricted to the use of two fingers, but more may be used such as the three fingers shown in Figure 3C. In addition, as with the other embodiments described herein, the embodiment described with reference to Figures 3A through 3C may also be calibrated so as to provide a user with an estimate of inner vessel diameter as well as localized temperature.

Page 16, line 19 to page 17, line 4:

Figures 4A through 4D illustrate preferred hand-type embodiments of the invention. In Figure 4A, a sensing head 402 includes one or more sensing cantilevered arms 404, each with a thermal sensor, surrounding a central member 410. The arms and central member are configured such that when the member is pulled from the proximal end, the arms fan outwardly from the contracted state of Figure 4A into a the expanded position, as shown in Figure 4B. Again, the arms are cantilevered to provide a

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relatively constant and uniform force against the vessel wall in the expanded state while avoiding excess pressure.

Page 19, lines 9-18:

The temperature sensors are preferably embedded slightly below the outer surfaces of the sensing arms or elements, along the surface closest to the inner wall of the vessel. The material covering the thermal sensor on the outer surface of the expanding [are or] element is chosen and configured so as to permit minimal thermal resistance between the thermal sensor and the outer surface of the sensing arm. This may be achieved by having a minimal thickness of material, or by choosing a material of low thermal resistance. In contrast, the bulk material of the expanding element is preferably chosen to have high thermal resistance and to be of a significantly greater thickness than the thickness of the material covering the thermal sensors on the outer surface of the sensing arms.

IN THE CLAIMS:

1. (Amended) A system for sensing the temperature of [an arterial wall or other] a vessel wall, including an arterial wall, the system comprising:

an elongated catheter having a distal end [with a temperature sensing tip] and a proximal end [including a manually operated expansion control];

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a [the] temperature sensing tip including one or more presentation elements, each element having a temperature sensor supported thereon;

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each [the] presentation [elements] element having a proximal end coupled to the distal end of the catheter and a distal end coupled to the distally protruding end of the filament [being physically coupled to] such that pulling on the manually operated expansion control [, such that operation of the control] causes each element [the elements and temperature sensors] to move from [between] a retracted position [, enabling the temperature sensing tip to be positioned in a section of the vessel to be measured,] to an expanded position enabling the sensor to be placed in contact or immediately proximate to the vessel wall, and pushing on the manually operated expansion control causes each presentation element to return to the retracted position from the [an] expanded position [, wherein the sensors are in contact or immediately proximate to the vessel wall]; and

a data unit operative to receive electrical signals from the temperature sensors and display information indicative of vessel wall temperature [as sensed by the sensors].

3. (Amended) The system of claim 1, wherein the presentation elements are thermally insulative so that the sensors are isolated from [the effects of] temperature fluctuations caused by blood flow or other ambient conditions.

5. (Amended) The system of claim 1, wherein the presentation elements are configured such that blood may continue to flow around the elements when the elements are in the expanded [condition] position.

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6. (Amended) [The] A system [of claim 1, wherein the presentation elements are fingers which expand outwardly in response to the manually operated expansion control.] for sensing the temperature of an arterial wall or other vessel, comprising:

an elongated catheter having a distal end and a proximal end;

a sliding filament that protrudes from both ends of the catheter, the protruding filament at the proximal end of the catheter acting as a manually operated expansion control;

a temperature sensing tip including a plurality of presentation elements in the form of cantilevered fingers which expand outwardly by pulling on the manually operated expansion control, each element having a temperature sensor supported thereon which is placed in contact or immediately proximate to the vessel wall during the expansion; and

a data unit operative to receive signals from the temperature sensors and display information indicative of vessel wall temperature as sensed by the sensors.

7. (Amended) The system of claim 6, wherein the cantilevered fingers are [cantilevered] configured to provide a relatively constant and uniform force against the vessel wall.

8. (Amended) The system of claim 6, wherein the fingers surround a central plunger coupled to the manually operated expansion control, such that pulling on the plunger causes the fingers to expand outwardly and pushing on the plunger causes the finger to turn to a contracted position.

9. (Amended) The system of claim 8, wherein the plunger is conically shaped [in the area where the plunger causes the fingers to spread].

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11. (Amended) The system of claim [8] 1, wherein the temperature sensing tip features a plurality of longitudinal slices [such that the presentation system assumes] forming a basket-like structure which flares out [in response to] when the manually operated expansion control is pulled, and which collapses when the control is pushed.